UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*, *ex rel.* ZACHARY SILBERSHER, **Plaintiffs,** **v.** **JANSSEN BIOTECH, INC., *et al.*,** **Defendants.**	**Civil Action No. 19-cv-12107-MEF-SDA** **SPECIAL MASTER ORDER**

THIS MATTER having come before the undersigned Special Master appointed by Order entered on March 18, 2024 (ECF No. 331); and the Order providing that the Special Master "shall oversee the schedule for completion of discovery, and all discovery disputes and motions related thereto, pursuant to procedures for practice that the Special Master may establish and modify as necessary", *id.* at 2, ¶ 2; and the Special Master, in order to address and resolve the respective discovery disputes between Relator Zachary Silbersher ("Relator") and Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC and Johnson & Johnson (collectively, "Defendants", and together with Relator, "Parties"), having entered an Order on April 12, 2024 (ECF No. 337) providing that counsel for the Parties shall "agree on a schedule for the filing and briefing of Relator's motion challenging Defendants' assertion of privilege", which is Relator's Motion for *In Camera* Review presently before the Special Master ("Motion"), *id.* at 1, ¶ 1; and the Special Master having entered an Order on April 23, 2024 (ECF No. 339) approving the Parties' agreed-upon briefing schedule with respect to the Motion; and

Relator having filed his moving papers on May 3, 2024 (ECF Nos. 345, 346, 347, and 348)[1]; and Defendants having filed their opposition to the Motion on May 24, 2024 (ECF Nos. 354 and 355); and Relator having filed his reply papers on June 10, 2024 (ECF Nos. 363 and 364); and the Special Master having scheduled argument on the Motion for August 21, 2024; and the argument having been rescheduled to September 19, 2024; and the Special Master having considered the issues, arguments and positions with respect to Relator's Motion; and good cause appearing for the entry of this Order

IT IS on this **4th** day of **October 2024 ORDERED** as follows:

1. Relator's Motion for *In Camera* Review is **DENIED**.

SPECIAL MASTER DECISION

The Special Master presumes the Parties are well acquainted with the pertinent facts and procedural history of this matter.

I. Relator's Motion for *In Camera* Review

Relator's Motion seeks the Special Master's *in camera* review of certain documents withheld or redacted by Defendants under the attorney-client privilege and/or work product doctrine. (ECF No. 347, p. 5.) According to Relator, the descriptions of withheld documents in Defendants' privilege logs[2], and the "nature" of redacted documents produced by Defendants, "reflect actions and communications in furtherance of Defendants' fraudulent scheme to overcharge federal and state governments for Zytiga", which included delaying generic entry and

[1] The Parties submitted unredacted versions of the moving brief, opposition, and reply brief directly to the Special Master. The unredacted versions were filed on the docket under seal. (ECF Nos. 346, 355, and 363.) The redacted versions are available at ECF Nos. 347, 354, and 364.

[2] Relator identifies three privilege logs provided by Defendants: one served on July 14, 2023; another served on September 12, 2023; and a third with a handful of entries not relevant to the issues in the Motion. (ECF No. 347, p. 26.)

inflating Zytiga's price for government payors. In so doing, Relator alleges, Defendants violated the False Claims Act, 31 U.S.C. § 3729-33.

Relator seeks an Order directing Defendants to submit to the Special Master for *in camera* review "the redacted and withheld documents … from July 3, 2013 to September 30, 2014" as described in "Exhibit 1" to the Counsel Declaration to the Motion. (ECF Nos. 345-1 and 345-3; *see also* ECF No. 347, p. 27.) "Exhibit 1", which was filed under seal but also submitted to the Special Master, consists of an extensive 120-page list of "Withheld Documents for *In Camera* Review", as well as a 2-page list of "Redacted Documents for *In Camera* Review", which appear to have been based, at least in part, on Defendants' privilege logs. According to Defendants, Relator wants the Special Master to review 965 withheld or redacted documents comprising thousands of pages. (ECF No. 354, p. 7.) Relator's reply brief also proposes an initial, "priority" *in camera* review of 200 documents.

Relator submits that the withheld and redacted documents relate to "three main components" of Defendants' alleged scheme. First, Relator argues Defendants obtained the '438 Patent through misleading statements or material omissions to the United States Patent and Trademark Office ("Patent Office"), including misstatements as to Zytiga's commercial success. In particular, Relator contends that co-administration of Zytiga with prednisone was, based on Defendants' own internal documents, a "principal weakness" of Zytiga's commercial success, contrary to what Defendants represented to the Patent Office (e.g., statements in Defendants' June 4, 2013 submission to the Patent Office). (ECF No. 347, pp. 12-15.) Relator also claims Defendants omitted the "actual reasons" and other factors for Zytiga's commercial success in violation of their duty to disclose those reasons. *Id.* at 15-17. According to Relator, Defendants

"appear to have fully expected that the patent would eventually be issued solely on the false commercial success argument that Defendants chose to let remain uncorrected." *Id.* at 20.

Second, Relator argues Defendants listed the '438 Patent in the Food and Drug Administration's ("FDA") "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") in order to obtain a stay of any FDA approval of generic competition for 30 months. Relator alleges Defendants did so despite knowing that the '438 Patent was obtained through the alleged fraud and thus could not be "reasonably asserted" against generic competitors. *Id.* at 25-26.

Third, Relator argues Defendants engaged in litigation against generic competitors which filed abbreviated new drug applications thereby extending Zytiga's loss of exclusivity date pending a judicial determination of the validity of the '438 Patent, despite the expectation of invalidation of the '438 Patent. *Id.* at 6-7. In sum, and based on citations to documents and testimony (portions of which have been redacted and otherwise protected under seal), Relator contends that Defendants "could not have believed in good faith that their fraudulent commercial success argument would withstand a validity challenge." *Id.* at 25. Additionally, Relator also points to Defendants' direction to their finance departments not to model business and revenue projections based on the '438 Patent's statutory expiration date. *Id.* at 9.

Relator submits that the standard to obtain *in camera* review is a "lenient" one, and that Relator need only make a *prima facie* showing of a factual basis adequate to support a good faith belief by a reasonable person that review of the documents may reveal evidence to establish that the crime-fraud exception applies. *Id.* at 7, 28. Relator contends that the advice and analyses of Defendants' in-house patent and litigation attorneys were "integral" to the implementation of

Defendants' fraudulent scheme. *Id.* at 10.[3] Relator requests that the Special Master review those documents *in camera* to "determine whether the attorney-client communications and work product generated in the course of [Defendants'] conduct was in furtherance of [the alleged] fraud." *Id.*

II. Defendants' Opposition to Motion for *In Camera* Review

In opposition to the Motion, Defendants advance a number of different contentions. First, Defendants assert Relator seeks to have the Special Master "undertake discovery for him" and to "try to find evidence" of the alleged fraud Relator has failed to uncover during discovery, which does not meet the evidentiary burden necessary to justify breaching the privileges at issue. (ECF No. 354, p. 7.) Defendants claim Relator has failed to identify evidence of fraud in any of the three components of the "new scheme" alleged in Relator's Motion—the prosecution of the '438 Patent, listing of the '438 Patent in the Orange Book, or the ensuing patent infringement litigation. *Id.* at 20.

Defendants note that Relator has not sought *in camera* review of any privileged communications from the "core prosecution period" including privileged communications relating to Johnson & Johnson's ("J&J") June 4, 2013 submission to the Patent Office, which Relator alleges constitutes the key fraudulent submission in the case. *Id.* at 20. Further, Defendants contend that Relator's new theory of the '438 Patent's listing in the Orange Book and assertion of the '438 Patent in litigation finds "scant purchase" in Relator's own Complaint and is thus beyond the scope of that pleading. *Id.* at 16-17. Defendants concede that Relator's pleading refers to the listing of the '438 Patent in the Orange Book and the assertion of the '438 Patent in litigation, but

[3] The Motion is limited to documents dated from July 3, 2013 (when Defendants received the Notice of Allowance for the '438 Patent) to September 30, 2014 (when Defendants listed the '438 Patent in the Orange Book).

notes that such references fail to meet the heightened particularity standard required under Rule 9(b). Thus, Defendants argue, Relator's new theories are barred.

In addition, Defendants argue that Relator has failed to provide the Special Master with the required "foundation in fact" to support Relator's allegations that: (1) J&J intentionally committed fraud; and (2) the privileged communications were in furtherance of the fraud. *Id.* at 16, 17, 19, 20. Defendants contend Relator's moving brief "quibbles with the merits of J&J's commercial success submission" but fails to offer any evidence that J&J "purposefully set out to, or did, defraud the" Patent Office. *Id.* at 8. Defendants further argue that if J&J did not defraud the Patent Office in the first instance in securing the issuance of the '438 Patent, then Relator lacks any foundation for the claim that J&J's subsequent actions to enforce the '438 Patent were also fraudulent.[4] *Id.* at 20.

Further, Defendants contend that Relator misconstrues documents which discuss the marketing challenges of Zytiga, which required a label indicating coadministration of abiraterone and prednisone, as evidence of a lack of belief in the therapeutic efficacy of that combination therapy. *Id.* at 9. Defendants also refute Relator's contention concerning any impact of the '438 Patent's issuance on financial planning documents, because internal financial planning materials could not have played any role in Defendants' purportedly false statements externally to government bodies.[5] *Id.* at 9-10.

Moreover, Defendants submit that the Special Master should exercise his discretion to deny *in camera* review because Relator's Motion is needlessly late and excessively broad. *Id.* at 10.

[4] Defendants also point to judicial rulings that J&J's assertion of the '438 Patent was not fraudulent. (ECF No. 354, pp. 8-9 (citations omitted).)

[5] Defendants note that J&J has since produced 269 financial planning documents to Relator, including 17 specifically covered by the Motion. (ECF No. 354, p. 10.)

They claim that Relator waited until the close of fact discovery to seek Special Master review of over 900 privileged communications, spanning thousands of pages, which do not relate to the fraudulent patent prosecution pled in Relator's Complaint. *Id.* at 10. In addition, Defendants emphasize that Relator failed to pursue discovery with reasonable diligence, and commenced a "blitz" of written discovery requests and depositions at the close of fact discovery. These belated efforts, Defendants argue, have been cumulative, overbroad, and wholly disproportionate as Relator searches for actionable evidence. *Id.* at 13-14. Defendants add that Relator has failed to explain why other privileged communications within the timeframe identified unrelated to Defendants' financial models could further any fraud, *id.* at 35-36, and that, at this juncture, Relator has now received numerous financial planning documents from J&J. *Id.* at 36.

Fundamentally, Defendants argue that the privileged communications at issue did not "further" any fraud. While they maintain Relator has not established any evidence of fraud, Defendants argue that the communications at issue were not used to facilitate, conceal, or contribute to a fraud and the crime-fraud exception does not apply to documents that may "merely provide evidence" of a supposed fraud. *Id.* at 10. Relatedly, Defendants contend that Relator has not shown how J&J actually *deceived* the Patent Office through any allegedly false misrepresentation. *Id.* at 22.

III. Relator's Reply Brief

Relator's reply brief advances the following arguments: (1) Relator's Complaint adequately pleads fraud; (2) Relator has made a *prima facie* case supporting *in camera* review; (3) Relator has identified a narrow set of documents for priority review; and (4) Relator's Motion is timely. (ECF No. 364, pp. 6, 9, 14.)

As to the first argument, Relator essentially contends that the Complaint "makes clear" that Defendants' fraudulent misstatements and omissions to the Patent Office are part and parcel of a larger fraudulent scheme. *Id.* at 6. Relator adds that Defendants' fraud continued through issuance of the '438 Patent, listing it in the Orange Book, and asserting it in litigation against generic manufacturers. Relator concedes that neither the Hatch-Waxman litigation nor the *inter partes* review proceedings "address[] the specific issue in the case—namely, fraud on the PTO during acquisition of the patent." *Id.* at 6, n. 3. Relator reiterates its assertion that "Defendants acted in furtherance of the fraudulent scheme" by fraudulently obtaining the Notice of Allowance for the '438 Patent, prosecuting the '438 Patent, and listing it in the Orange Book, despite lacking a "good faith belief" that the '438 Patent would survive a validity challenge. Relator claims "[t]hese have always been Relator's allegations, and the evidence produced to date has strengthened Relator's claims." *Id.*

As to the second argument, Relator claims he has established a factual basis under the applicable standard for *in camera* review by "citing ample evidence in support of his allegations." *Id.* at 9. Among other examples, Relator focuses on various evidence of Defendants' "major change" to their long-range financial forecast *after* receiving the Notice of Allowance, as well as the content of Defendants' privilege log entries, which "strongly suggest", or otherwise "may show evidence of" Defendants acting in furtherance of fraud. *Id.* at 10-13.

As to the third argument, Relator proposes that the Special Master first review *in camera* a subset of 200 documents and, if "evidence of actions in furtherance of fraud" is identified, then Relator would seek full review of all documents at issue. *Id.* at 4, 14. Relator underscores that any advice or actions of Defendants' counsel in furtherance of the claimed fraud fall within the crime-fraud exception. Relator surmises that the privileged documents "would include": (1) documents

indicating that Defendants believed that the '438 Patent would not survive judicial or agency scrutiny; (2) documents relating to the recommendation to list the '438 Patent in the Orange Book or to assert it against competitors; and (3) documents relating to Defendants' internal planning for generic entry when patent litigation or *inter partes* review was "likely to be decided". Thus, Relator argues, he has made a *prima facie* case sufficient to trigger *in camera* review of the documents at issue.

As to the fourth argument, Relator maintains that the Motion is not untimely. Relator points to Defendants' past efforts to seek the Court's permission for a voluntary waiver of privilege over Defendants' patent prosecution documents as well as the Court's assistance in defining the scope of the waiver. *Id.* at 14, 15. Relator also notes that Defendants thwarted those efforts, "stood on" their privileges, and proposed completing depositions to "see how the privilege issues play out", with the parties proceeding with this course of action. For these reasons, Relator maintains the Motion is not untimely.

Relator notes that Defendants' privilege logs and redactions "suggest" Defendants have "wrongly shielded" communications in furtherance of Defendants' fraud. *Id.* at 4. Relator also claims the documents, when compared to the privilege logs and redactions, "illuminate a key time when the crime-fraud exception appears particularly likely to expose damaging evidence." *Id.* He submits that the "tempo, context, and audience" for Defendants' communications "strongly indicate" they were in furtherance of the fraudulent scheme. *Id.* at 5. Relator underscores the "abundant evidence" of the falsity of Defendants' representations to the Patent Office. *Id.*

IV. Legal Standard

a. Relevance and Scope of Discovery.

"The precise boundaries of the Rule 26 relevance standard depend upon the context of each particular action, and the determination of relevance is within the discretion of the District Court." *Graco, Inc. v. PMC Global, Inc.*, No. 08-01304, 2011 WL 1114233, at *28 (D.N.J. Mar. 24, 2011) (citing *Barnes Found. v. Twp. of Lower Merion*, No. 96-00372, 1996 WL 653114, at *1 (E.D.Pa. 1996)). Under Rule 26, "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1).

Courts have "broad discretion in managing requests for discovery and determining the appropriate scope of discovery." *Falato v. Fotografixusa, L.L.C.*, No. 09-05232, 2013 WL 1846807, at *3 (D.N.J. Apr. 30, 2013) (citation omitted). "Rule 26(b)(2) vests the court with the authority to limit a party's pursuit of otherwise discoverable information." *Gilmore v. Jones*, No. 21-13184, 2022 WL 267422, at *2 (D.N.J. Jan. 28, 2022); *see also Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3d Cir. 1999) ("Although the scope of discovery under the Federal Rules is unquestionably broad, this right is not unlimited and may be circumscribed.").

b. Attorney-Client Privilege and Work Product Doctrine

The attorney-client privilege protects from disclosure confidential communications made between attorneys and clients for the purpose of obtaining or providing legal assistance to the client. *In re Grand Jury*, 705 F.3d 133, 151 (3d Cir. 2012) (citing *In re Teleglobe Commc'ns Corp.*, 493 F.3d 345, 359 (3d Cir. 2007)). By contrast, the work product doctrine "promotes the adversary system by enabling attorneys to prepare cases without fear that their work product will be used

against their clients." *In re Grand Jury*, 705 F.3d at 151 (citing *In re Chevron Corp.*, 633 F.3d 153, 164 (3d Cir. 2011)). "Though both operate to protect information from discovery, the work-product doctrine and the attorney-client privilege serve different purposes." *In re Chevron Corp.*, 633 F.3d at 164. Of course, such protections are not absolute. *In re Grand Jury*, 705 F.3d at 151.

c. Crime-Fraud Exception

"Typically, application of the crime-fraud exception begins with 'presentation of the factual basis for a good faith belief that the exception would apply,' followed by 'in camera evaluation of the material by the court,' and the provision of an opportunity to be heard to the party opposed to disclosure." *In re Neurontin Antitrust Litigation*, 801 F.Supp.2d 304, 307 (D.N.J. 2011) (quoting *Prudential Ins. Co. of Am. v. Massaro*, 47 Fed.Appx. 618, 619 (3d Cir. 2002)). "'[T]he decision to engage in in camera review implicates a much more lenient standard of proof than the determination to apply the crime/fraud exception[.]'" *In re Neurontin*, 801 F.Supp.2d at 307 (quoting *Haines v. Liggett Group, Inc.*, 975 F.2d 81, 96 (3d Cir. 1992)).

"Once the documents are before the court for *in camera* review, the party invoking the crime-fraud exception must make 'a prima facie showing that (1) the client was committing or intending to commit a fraud or crime and (2) the attorney-client communications were in furtherance of that alleged crime or fraud.'" *In re Neurontin*, 801 F.Supp.2d at 307 (quoting *In re Grand Jury Subpoena*, 223 F.3d at 217). "It is the purpose of the crime-fraud exception to the attorney-client privilege to assure that the seal of secrecy between lawyer and client does not extend to communications made for the purpose of getting advice for the commission of a fraud or crime." *In re Neurontin*, 801 F.Supp.2d at 307 (quoting *United States v. Zolin*, 491 U.S. 554, 563 (1989)).

The Third Circuit defined the relevant standard for the crime-fraud exception in holding that "[w]here there is a reasonable basis to suspect that the privilege holder was committing or intending to commit a crime or fraud and that the attorney-client communications or attorney work product were used in furtherance of the alleged crime or fraud, this is enough to break privilege." *In re Grand Jury*, 705 F.3d at 153. It is "[the] client's intentional 'misuse [of] [an] attorney's advice in furtherance of' 'wrongdoing' undertaken for an 'improper purpose,' [that] triggers the crime-fraud exception. *In re Abbott Laboratories*, 96 F.4th 371, 380 (3d Cir. 2024) (quoting *In re Grand Jury*, 705 F.3d at 151, 157). "All that is necessary is that the client misuse or intend to misuse the attorney's advice in furtherance of an improper purpose[.]" *In re Grand Jury*, 705 F.3d at 157. To satisfy the "in furtherance of" element of the crime-fraud exception, "a logical link must exist between the privileged communication and the proposed crime or fraud." *Prudential Ins. Co. v. Massaro*, No. 97-02022, 2000 WL 1176541, at *10 (D.N.J. Aug. 14, 2000). "That is, the legal advice 'must relate to future illicit conduct by the client; it [must be] the causa pro causa, the advice that leads to the deed.'" *In re Neurontin*, 801 F.Supp.2d at 310 (citing *Haines*, 975 F.2d at 90).

"It does not suffice that the communications may be related to a crime; … they must actually have been made with an intent to further an unlawful act." *In re Neurontin*, 801 F.Supp.2d at 310 (citing *United States v. White*, 887 F.2d 267, 271 (D.C.Cir. 1989)). The crime-fraud exception does not extend to communications that "merely relate to the crime or fraud" or "merely opine[] on the lawfulness of a particular course of action." *In re Abbott Laboratories*, 96 F.4th at 383 (citations omitted). "Because it is difficult to determine whether a document contains communications used in furtherance of … fraud, courts sometimes review the allegedly privileged

materials *in camera* to decide whether the crime-fraud exception applies to preclude the privilege." *In re Grand Jury*, 705 F.3d at 151.

V. Special Master's Decision

The Special Master finds that Relator has not met his burden of establishing a factual basis adequate to support a good faith belief by a reasonable person that *in camera* review of the materials at issue may reveal evidence to establish the claim that the crime-fraud exception applies. *See Zolin*, 491 U.S. at 572. Mere claims of fraud, or even evidence of fraud, without more, is insufficient to meet the requisite showing. Relator has not presented an adequate basis to suspect that there was an "intentional misuse" of an attorney's advice "in furtherance of wrongdoing" for an "improper purpose". *In re Abbott Laboratories*, 96 F.4th at 380 (quoting *In re Grand Jury*, 705 F.3d at 151, 157. Thus, the Motion is denied.

The case of *In re Neurontin Antitrust Litigation*, 801 F.Supp.2d 304 (D.N.J. 2011) is instructive.[6] There, Class Plaintiffs sought *in camera* review of documents deemed privileged by Defendants Pfizer, Inc. and Warner-Lambert Company LLC to "determine whether the crime-fraud exception applies." *In re Neurontin*, 801 F.Supp.2d at 306. Class Plaintiffs directly purchased from Defendants Neurontin (a brand-name version of the drug compound gabapentin anhydrous) and alleged that Pfizer engaged in an anti-competitive scheme to maintain a market monopoly over gabapentin products in violation of Section 2 of the Sherman Act, 154 U.S.C. § 2. They also alleged that Pfizer's actions delayed entry of generic gabapentin into the market, and excluded market entry by generic manufacturers, which caused Class Plaintiffs to pay non-competitive prices for generic gabapentin. Class Plaintiffs alleged that Pfizer carried out the

[6] While this decision is discussed in Defendants' opposition to the Motion, Relator does not address or discuss this decision at all in his moving brief or reply brief. Nonetheless, both sides addressed the significance of this decision at oral argument.

scheme by obtaining additional patents it improperly listed in the Orange Book, manipulating the patent approval process to delay generic entry, prosecuting multiple sham litigation on the patents at issue, and engaging in "fraudulent off-label promotion" to convince physicians to prescribe Neurontin for non-approved uses. *In re Neurontin*, 801 F.Supp.2d at 306, n.1.

Class Plaintiffs offered "two potential bases" upon which the Court might find a fraud or crime to properly invoke the crime-fraud exception after *in camera* review, specifically: (1) Defendants' off-label promotion of Neurontin and the filing of the '479 patent litigation as part of a scheme to protect profits generated by Neurontin; and (2) potentially fraudulent statements to two different judges in the course of that litigation and related litigation about Defendants' off-label promotion. *Id.* at 307. Notably, Pfizer had pled guilty to engaging in an illegal off-brand promotion in 1995 and 1996, and a Massachusetts court in civil trial proceedings found that those activities continued into 2004. Warner-Lambert also acknowledged its illegal conduct, despite initially and repeatedly representing to the Court that it did not engage in off-label promotion.

While the Court in *In re Neurontin* was "deeply troubled" by the "disturbing" conduct which Pfizer admitted, it nevertheless found that Class Plaintiffs "have not set forth a reasonable basis upon which to conclude that *in camera* review would demonstrate that communications about the prosecution of the '479 Patent litigation were made with an intent to further unlawful promotion or profit-making schemes involving off-label marketing." *Id.* at 310. The Court found that Class Plaintiffs did not present any basis beyond their own allegations on which the Court could conclude that Pfizer's willingness to engage in misconduct with regard to off-label promotion and the filing of the '479 Patent litigation "necessarily mean[t] that Pfizer filed the '479 Patent Litigation with ulterior motives." *Id.* The Court also found the connection between the off-

label activities and the filing of the '479 Patent litigation "too attenuated" for the Court to form a good faith belief that the two efforts were part of a singular anti-trust scheme.

By contrast, however, the Court *did* find that Pfizer's several representations to the Court regarding the off-label promotion, which were contradicted by Pfizer's later admission in its guilty plea and by judicial determinations in related litigation, *did* entitle Class Plaintiffs to *in camera* review of privileged communications. The Court did not reach the question of whether the crime-fraud exception applied, but found that, if Pfizer's statements were untrue, Class Plaintiffs were entitled to probe the knowledge of persons involved in those communications, and a reasonable person might conclude that the statements were made as part of a scheme to hide Pfizer's misconduct. The circumstances in that case, "taken together", provided a factual basis adequate to support a good faith belief by a reasonable person that in camera review of the materials may reveal evidence to establish the claim that the crime-fraud exception applies. *Id.* at 311.

The distinguishable facts of *In re Neurontin* weigh in favor of denying Relator's Motion. In that case, it was established that Pfizer's representations to the Court were refuted by Pfizer's later guilty plea along with judicial rulings in related litigation. The particular circumstances in *In re Neurontin* persuaded that Court to find that *in camera* review was warranted. By contrast, here, while Relator contends that Defendants obtained the '438 Patent through misleading statements or material omissions to the Patent Office, Defendants have not conceded much less pled guilty to having made any misleading statements or material omissions, and in fact, these allegations remain disputed.

For purposes of deciding the pending Motion only, the Special Master concludes that Relator's disagreement with the merits of Defendants' commercial success arguments in securing the '438 Patent is not a sufficient factual basis to support a good faith belief by a reasonable person

that *in camera* review may reveal evidence to establish his claim that the crime-fraud exception applies.[7] There is no dispute that documents and testimony in the case have described the FDA's co-administration requirement as a "weakness", but Defendants have cited considerable testimony that a distinction is to be made between the marketing of Zytiga (i.e., the weakness) and the therapeutic and clinical benefits of Zytiga (i.e., the strength and efficacy of the drug). Defendants also fairly dispute Relator's claim that J&J concealed the "actual reasons" for Zytiga's commercial success from the Patent Office. (ECF No. 354, p. 25.) Relator has not met his burden of showing that Defendants' commercial success arguments were made in furtherance of an intent to deceive the Patent Office to warrant *in camera* review.

Further, the Special Master finds that Relator's reliance on J&J having listed the '438 Patent in the Orange Book and having commenced patent infringement litigation to enforce the '438 Patent unavailing. Not only do these theories fall outside the claims set forth in Relator's pleading, but they have also been rejected in prior litigation and are refuted by evidence in the record. In that prior litigation, the Court found that Janssen's infringement action, while unsuccessful, was "not objectively baseless", and that J&J had "probable cause" to bring the patent infringement action. *La. Health Serv. & Indemnity Co. v. Janssen Biotech, Inc.*, No. 19-14146, 2021 WL 4988523, at *8 (D.N.J. Oct. 27, 2021). Moreover, Defendants' listing of the '438 Patent in the Orange Book to stay approval of generic competition, along with Defendants' initiation of litigation against generic competitors to extend Zytiga's loss of exclusivity date, are somewhat attenuated with respect to the fraud that is alleged by Relator. Thus, the Special Master cannot form a good faith belief that these efforts have a sufficient connection to Defendants' *intentional*

[7] The Special Master's findings as set forth in this Order and Opinion are limited to the issues and disputes encompassed in Relator's Motion only.

misuse of attorney advice for purposes of deciding whether *in camera* review would be appropriate. The Special Master finds that Relator has not persuasively established a "logical link" between these purportedly fraudulent activities and the privileged communications identified by Relator that are at issue.

Additionally, the Special Master does not find that the alleged elements of J&J's long-range financial planning ("LRFPs") indicate fraud on the part of Defendants sufficient to warrant *in camera* review. Merely that the LRFPs do not assume generic competition until the '438 Patent's expiration in 2027 does not establish J&J knew or believed that the '438 Patent was obtained by fraud. Such a theory is somewhat speculative and not backed by adequate proof, and J&J's efforts to calculate financial forecasts that account for risks and uncertainties in the future do not reflect fraud for purposes of countenancing *in camera* review or recognizing the crime-fraud exception.[8]

Moreover, the Special Master is not persuaded that Relator has shown the privileged communications relating to the LRFPs were made in furtherance of, and actually contributed to, any alleged fraud. Relator argues that the LRFPs show that J&J's counsel lacked a good faith belief in the success of the '438 Patent in litigation. This contention is argumentative, and does not establish that any privileged communications actually *furthered* the fraud. Relator has not convincingly shown that the LRFPs, for instance, "concealed", "facilitated", or otherwise "contributed to" the allegedly false statements to the Patent Office or any government healthcare

[8] Defendants' unredacted brief filed under seal devotes several pages to summarizing relevant testimony with respect to the formulation and development of several of J&J's LRFPs. While much of the testimony and documents have been concealed in the redacted version of the brief, ECF No. 354, pp. 27-31, the Special Master has reviewed the unredacted brief in its entirety, and is satisfied that the LRFPs do not evidence a lack of any good faith belief on J&J's part in its own patents.

program. At best, this may be "evidence" of the supposed fraud, but that falls short of demonstrating a "furtherance" of the supposed fraud under the applicable standard.

Relator elsewhere argues that the crime-fraud exception can apply to the "assertion of frivolous legal claims" and cites *In re Abbott Labs.*, 96 F.4th 371 (3d Cir. 2004) for this proposition. (ECF No. 364, p. 8.) But in *Abbot Labs.*, as Relator points out, the Third Circuit's decision was premised in part on the finding that the underlying lawsuit was "baseless." Here, there has been no such finding. Instead, Judge McNulty in related litigation ruled that J&J "had probable cause to bring [the] infringement action." *La. Health Serv.*, 2021 WL 4988523, at *10. Judge McNulty also found that, while the '438 Patent was ultimately invalidated, the Court's "judgment call … could be made differently by another jurist." *BTG Int'l Lt'd v. Amneal Pharms., Inc.*, No. 16-02449, ECF No. 48 at 60:13-14 (Nov. 5, 2018). To the extent that is distinguishable from *Abbot Labs.*, Relator's reliance on that decision is unavailing.

Finally, and notwithstanding the foregoing, the Special Master also declines to conduct the requested *in camera* review that Relator proposed in his Motion. The volume of materials sought for review exceeds 900 documents and spans thousands of pages, and the relative importance of these documents has not been established (indeed, Relator nowhere mentions that the documents at issue are "relevant"). While Relator alternatively proposed an *in camera* review of 200 documents in his reply brief, that request is also somewhat broad, and Relator provided no rationale as to why or how those 200 documents were selected or identified.

VI. Conclusion

For the reasons set forth above, Relator's Motion for *In Camera* Review is **DENIED**.

IT IS SO ORDERED.

Dated: October 4, 2024

s/ Douglas E. Arpert
DOUGLAS E. ARPERT
SPECIAL MASTER